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<b>(54) Title:</b> BIODEGRADABLE CHEWING GUM BASES INCLUDING PLASTICIZED POLY(D,L-LACTIC ACID) AND COPOLYMERS THEREOF  <b>(57) Abstract</b>  Gum base and chewing gums including plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) are provided as well as methods of making same.		

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## SPECIFICATION

### TITLE

BIODEGRADABLE CHEWING GUM BASES INCLUDING PLASTICIZED POLY(D,L-LACTIC ACID) AND COPOLYMERS THEREOF

5

### BACKGROUND OF THE INVENTION

The present invention relates generally to chewing gum compositions and methods for making same. More specifically, the present invention relates to chewing gum compositions that are more environmentally acceptable than typical compositions.

10 For hundreds of years, people have enjoyed chewing gum like substances. In the late 1800's, the predecessor to today's chewing gum compositions were developed. Today chewing gum is enjoyed daily by millions of people worldwide.

Chewed gum is usually disposed of in the wrapper that initially houses the chewing gum. Likewise, chewed gum can be disposed of in other substrates by wrapping  
15 the substrate around the chewing gum.

Although chewed gum can be easily disposed of without creating any problems, chewing gum when improperly disposed of can create environmental issues. In this regard, the improper disposal of chewing gum, e.g., expectorating the chewing gum on a sidewalk, floor, or like area can create a nuisance. Typically, these gum cuds are  
20 mainly composed of a water insoluble masticatory part which is represented by the gum base. Due to its formulation, these gum cuds have an adhesive like characteristic. Therefore, the chewed gum cuds can stick to surfaces on to which it is placed. This can create issues if the chewed gum cuds are improperly discarded.

Rapidly biodegradable chewing gums would be a solution to this problem.  
25 Conventional chewing gums are formulated from natural and/or synthetic elastomers and resins. Although some natural resins and elastomers such as Chicle, Jelutong, natural rubber, esters of wood rosin, and polyterpene resins may be still used in gum bases, today synthetic polymers such as styrene-butadiene rubber (SBR), butyl rubber, polyisobutylene, and poly(vinyl acetate) are the dominant masticatory substances.  
30 Unfortunately, these synthetic polymers are inherently resistant to biodegradation.

There have been at least a couple of attempts at providing biodegradable chewing gum. Published PCT Application No. PCT/US97/11008 discloses lactic acid based

copolymers for use as a masticatory substance. The chewing gum base comprises approximately 3 to about 99% by weight poly(lactic acid) copolymers selected from the group consisting of poly(lactic acid-dimer fatty acid-oxazoline) copolymers and poly(lactic acid-diol-urethane) copolymers.

- 5 U.S. Patent No. 5,672,367 sets forth biodegradable chewing gums based on poly(lactic acid-co-caprolactone) elastomers. Although the elastomers may have desirable chewing characteristics, the toxic caprolactone monomer residues may prevent the elastomers from being used as a masticatory substance.

#### SUMMARY OF THE INVENTION

- 10 The present invention provides a gum base, and resultant chewing gum, that is environmentally friendly. As used in the application, the term "environmentally friendly" refers to chewing gum compositions that: will degrade rapidly; can be easily removed from indoor or outdoor surfaces; can be ingested after chewing; and/or will dissolve in the mouth after a period of chewing.

- 15 Pursuant to the present invention, environmentally friendly chewing gum bases are provided that are biodegradable. These chewing gum bases are formulated with poly(D,L-lactide acid) and poly(D,L-lactide acid-co-glycolic acid).

To this end, in an embodiment, the present invention provides a chewing gum comprising: plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid).

- 20 In an embodiment, the plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) have a crystallinity of less than about 18%.

In an embodiment, the poly(D,L-lactic acid) has a crystallinity of less than about 10%.

- In an embodiment, the poly(D,L-lactic acid) contains at least 5 mole percent of  
25 at least one component chosen from the group consisting of D-lactic acid and D-lactide segments.

In an embodiment, the poly(D,L-lactic acid) has a molecular weight of from approximately 2000 to about 2,000,000 g/mol.

- In an embodiment, the poly(D,L-lactic acid) has a molecular weight of from  
30 approximately 10,000 to about 500,000 g/mol.

In an embodiment, the poly(D,L-lactic acid-co-glycolic acid) has a crystallinity

of less than about 10%.

In an embodiment, the poly(D,L-lactic acid-co-glycolic acid) includes approximately 20 to about 70 mole percent of at least one component chosen from the group consisting of glycolic acid and glycolide.

- 5 In an embodiment, the poly(D,L-lactic acid-co-glycolic acid) has a molecular weight of approximately 10,000 to about 500,000 g/mol.

In an embodiment, the chewing gum includes at least one plasticizer chosen from the group consisting of glycerides (mono-, di-, and tri-), adipates, citrates, poly(ethylene glycol), poly(propylene glycol), and phthalates.

- 10 In another embodiment, the present invention provides a gum base. The gum base comprises plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid).

In an embodiment, the plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) have a crystallinity of less than about 18%.

- 15 In an embodiment, the poly(D,L-lactic acid) has a crystallinity of less than about 10%.

In an embodiment, the poly(D,L-lactic acid) contains at least 5 mole percent of at least one component chosen from the group consisting of D-lactic acid and D-lactide segments.

- 20 In an embodiment, the poly(D,L-lactic acid) has a molecular weight from approximately 2000 to about 2,000,000 g/mol.

In an embodiment, the poly(D,L-lactic acid) has a molecular weight from approximately 10,000 to about 500,000 g/mol.

- 25 In an embodiment, the poly(D,L-lactic acid-co-glycolic acid) has a crystallinity of less than about 10%.

In an embodiment, the poly(D,L-lactic acid-co-glycolic acid) includes approximately 20 to about 70 mole percent of at least one component chosen from the group consisting of glycolic acid and glycolide.

- 30 In an embodiment, the plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) comprises approximately 10 to about 70% by weight of the gum base.

In yet another embodiment of the present invention, a method of manufacturing

gum base is provided comprising the step of plasticizing poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) and adding a resultant product to other gum base components.

In an embodiment of the method, the resultant product comprises approximately  
5 20 to about 70 mole percent of the gum base.

Additionally, the present invention provides a method of manufacturing chewing gum comprising the step of adding a gum base including plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) to a water soluble portion.

It is an advantage of the present invention to provide an environmentally friendly  
10 chewing gum base.

It is a further advantage of the present invention to provide a chewing gum that is biodegradable.

Still further, it is an advantage of the present invention to provide a chewing gum composition made from a biodegradable chewing gum base.

15 Another advantage of the present invention is to provide a degradable chewing gum containing an environmentally friendly chewing gum base.

Moreover, an advantage of the present invention is to provide a chewing composition that when chewed, if improperly discarded onto a surface, can be easily removed therefrom.

20 Additional features and advantages of the present invention are described in and will be apparent from the detailed description of the presently preferred embodiments and from the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates, graphically, DSC thermographs of virgin and plasticized  
25 poly(D,L-lactic acid).

Figure 2 illustrates, graphically, a comparison of poly(D,L-lactic acid) base on conventional base rheology.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides improved gum bases. Specifically, the present  
30 invention provides gum bases that are environmentally friendly. In this regard, the gum bases are biodegradable. Additionally, improved chewing gums as well as ingredients

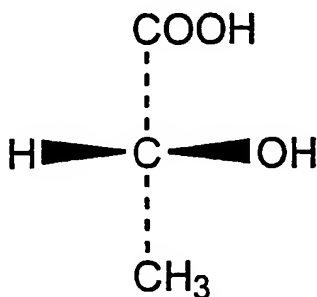
used for the gum bases are described.

The gum base contains amorphous poly(D,L-lactic acid) and poly(D,L-lactide acid-co-glycolic acid). It should be noted that in the art poly(D,L-lactic acid) may also be referred to as poly(D,L-lactide) and poly(D,L-lactic acid-co-glycolic acid) may also be referred to as poly(D,L-lactide-co-glycolide).

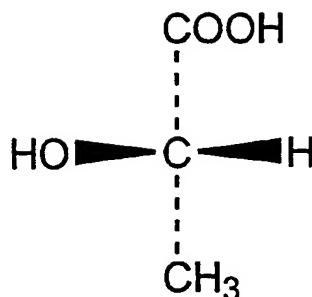
Both polylactide and the copolymers thereof can degrade automatically to carbon dioxide and water by microorganisms. Pure poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) lack desirable elasticity at room temperature ( $T_g=35-45^\circ\text{C}$ ). However, it has been found that they can be softened by a number of plasticizers. The plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) possess good elasticity, and therefore can replace both the rubbers and resins in a conventional gum base.

The gum bases including the plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acids) also contain other conventional, but environmentally friendly ingredients. These ingredients include calcium carbonate, hydrogenated vegetable fats, waxes, and glycerol esters. Because the resultant gums are formulated with all biodegradable ingredients, the gum cuds possess complete biodegradability.

Lactic acid has two enantiomeric forms due to the asymmetrically created carbon center: dextrorotatory or D-lactic acid (as shown below at I); and levorotatory or L-lactic acid (as shown below at II).



Symbol I. D-Lactic acid



Symbol II. L-Lactic acid

10        Consequently, the poly(lactic acid) polymer has two corresponding enantiomeric forms also: PDLA; and PLLA. The racemic mixture of the two is poly(D,L-lactic acid). Both PDLA and PLLA are highly crystalline. The copolymers poly(D,L-lactic acid) are much less crystalline or even amorphous depending on the monomer ratio. Literature has shown that PLLA has 38% crystallinity, while poly(D,L-lactic acid) with 5 mole percent  
15 D-lactic acid has only 18% crystallinity. At about a 1:1 ratio, poly(D,L-lactic acid) is amorphous.

      Since the common form, PLLA, is highly crystalline and has a glass transition temperature (T<sub>g</sub>) around 58°C, it is rigid at room temperature and, not suitable as a chewing gum masticatory ingredient. However, the Poly(D,L-lactic acid) form is  
20 amorphous, and has a T<sub>g</sub> of about 50°C. It can be plasticized by a number of softeners, resulting in much more rubbery and elastic materials. These plasticized materials offer the desirable chewing characteristics required by chewing gums. It has also been found that poly(D,L-lactic acid) degrades much faster than crystalline PLLA.

      The plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid)  
25 can be used in a variety of chewing gum products. In general, a chewing gum composition typically comprises a water-soluble bulk portion, a water-insoluble chewable gum base portion, and typically water-insoluble flavoring agents. The water-soluble portion dissipates with a portion of the flavoring agent over a period of time during chewing. The gum base portion is retained in the mouth throughout the  
30 chew. The term chewing gum refers to both a chewing and bubble type gum in its general sense.



The water-insoluble portion of the gum typically may contain any combination of elastomers, vinyl polymers, elastomer plasticizers, fillers, softeners, waxes and other optional ingredients such as colorants and antioxidants.

The variety of gum base ingredients typically used provide the ability to modify  
5 the chewing characteristics of gums made from the gum base.

Elastomers provide the rubbery, cohesive nature to the gum which varies depending on this ingredient's chemical structure and how it is compounded with other ingredients. Elastomers suitable for use in the gum base and gum of the present invention include poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid).  
10 Poly(D,L-lactic acid) may have a D-isomer content from approximately 5 to about 95 mol%. Poly(D,L-lactic acid-co-glycolic acid) may have a glycolic monomer content of from approximately 20 to about 70 mol%.

The elastomers for use in a gum base or gum of the present invention are plasticized poly(D,L-lactic acid)s alone or in combination with other typical gum base  
15 and gum ingredients. However, the gum base and gum are free of non-degradable elastomers such as butadiene-styrene copolymers (SBR), isobutylene-isoprene copolymers (Butyl rubber), polybutadiene, polyisobutylene, and vinyl polymeric elastomers (polyvinyl acetate, polyethylene, vinyl acetate/vinyl laurate, vinyl acetate/vinyl stearate, ethylene/vinyl acetate) or mixtures thereof.

20 Other optional ingredients such as antioxidants may also be used in the gum base.

Antioxidants prolong shelf-life and storage of gum base, finished gum or their respective components including fats and flavor oils. Antioxidants suitable for use in gum base or gum of the present invention include butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), beta-carotenes, tocopherols, acidulants such as Vitamin  
25 C, propyl gallate, and other synthetic and natural types or mixtures thereof.

Preferably, the antioxidants used in the gum base are butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), tocopherols, or mixtures thereof.

Waxes aid in the solidification of gum bases and improving shelf-life and texture. Wax crystal also improves the release of flavor. The smaller crystal size allows slower  
30 release of flavor since there is more hindrance of the flavor's escape from this wax versus a wax having larger crystal sizes.

Preferably, the gum base and gum of the present invention employs waxes containing little if any normal-alkanes, or straight-chained alkanes as they may be called, and contain predominantly iso-alkanes, or branched chain alkanes, having carbon chain lengths greater than 30. Formulation of some gum bases of this type may result in these  
5 gum bases being more homogeneous and that have ingredients exhibiting more compatibility with each other. Again, this compatibility is the result of the branched nature of iso-alkanes physically interacting, on a molecular level, with the branched nature of the other gum base ingredients.

Synthetic waxes are produced by means atypical of petroleum wax production  
10 and thus are not considered petroleum wax. These synthetic waxes may be used in accordance with the present invention and may be included optionally in the gum base and gum.

The synthetic waxes may include waxes containing branched alkanes and copolymerized with monomers such as but not limited to polypropylene and polyethylene  
15 and Fischer-Tropsch type waxes. Polyethylene wax is not in the same category as polyethylene, a polymer of ethylene monomers. Rather, polyethylene wax is a synthetic wax containing alkane units of varying lengths having attached thereto ethylene monomers.

Elastomer plasticizers vary the firmness of the gum base. The plasticizers are  
20 glycerol ester of partially hydrogenated rosin, glycerol ester of polymerized rosin, glycerol ester of partially dimerized rosin, glycerol ester of rosin, glycerol ester of tall oil rosin, pentaerythritol esters of partially hydrogenated rosin, partially hydrogenated methyl esters of rosin, pentaerythritol ester of rosin, synthetic elastomer plasticizers such as terpene resins derived from alpha-pinene, beta-pinene and/or d-limonene and mixtures  
25 thereof. As revealed by ASTM D5210-91 test results, some of these plasticizers have certain biodegradability therefore can be used in the present invention as softeners to poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid).

The elastomer plasticizers used may be of one type or of combinations of more than one. Typically, the ratios of one to the other are dependent on each respective  
30 softening point, on each effect on flavor release, and on each respective degree of tack they cause to the gum.

Fats modify the texture of the gum base by introducing sharp melting transition during chewing. Fats suitable for use in the gum base and gum of the present invention include triglycerides of non- hydrogenated, partially hydrogenated and fully hydrogenated cottonseed oil, soybean oil, palm oil, palm kernel oil, coconut oil, safflower oil, tallow oil, cocoa butter, medium chained triglycerides and the like.

The preferred fats include unsaturated, partially saturated or fully saturated oils that contain, as one or more of their constituent groups, fatty acids of carbon chain length of from 6 to 18. Monoglycerides, diglycerides, acetylated monoglycerides, distilled mono- and diglycerides and lecithin may, from their manufacturing processing, contain triglyceride levels less than 2 percent by weight. Mono- and diglycerides maybe considered as being of the same family as fats (triglycerides), or would be in a family of their own, namely emulsifiers.

Optional fillers used in gum base modify the texture of the gum base and aid in processing. Fillers suitable for use in the gum base and gum of the present invention include carbonate or precipitated carbonated types such as magnesium and calcium carbonate, ground limestone and silicate types such as magnesium and aluminum silicate, clay, alumina, talc, as well as titanium oxide, mono-, di- and tricalcium phosphate, cellulose polymers such as ethyl, methyl and wood or mixtures thereof. The fillers can also be organic powders such as polystyrene, polyethylene, oat fiber, wood fiber, apple fiber, zein, gluten, gliadin, casein, etc. For the present invention, natural organic fillers such as zein, oat fiber, gluten, casein, and cellulose are preferred since they will aid in faster biodegradation.

Particle size can have an effect on texture, cohesiveness, density and processing characteristics of the gum base and its compounding. The smaller the particle size, the more dense and cohesive the final gum base is. Also, by selecting fillers based on their particle size distribution, initial mass compounding may be varied, thus allowing alteration of the compounding characteristics of the initial mass during gum base processing and ultimately the final chew characteristics of gums made from these gum bases. Mean particle size for calcium carbonate and talc fillers typically range from about 0.1 micron to about 15 microns.

The starting mass preferably may comprise one or more of fillers, poly(D,L-lactic

acid) or poly(D,L-lactic acid-co-glycolic acid) elastomer, and plasticizers. Preferably, the starting mass is comprised of some or all of the poly(D,L-lactic acid) or poly(D,L-lactic acid-co-glycolic acid) elastomer, some or all of the filler and some or all of the plasticizer.

5           Flavorants and colorants impart characteristics or remove or mask undesired characteristics. Colorants may typically include FD&C type lakes, plant extracts, fruit and vegetable extracts and titanium dioxide. Flavorants may typically include cocoa powder, heat-modified amino acids and other vegetable extracts.

          Gum bases are typically prepared by adding an amount of the elastomer,  
10 plasticizer and filler to a heated (50-240°F) sigma blade mixer with a front to rear speed ratio of from about 1.2:1 to about 2:1, the higher ratio typically being used for chewing gum base which requires more rigorous compounding of its elastomers.

          The initial amounts of ingredients comprising the initial mass may be determined by the working capacity of the mixing kettle in order to attain a proper consistency and  
15 by the degree of compounding desired to break down the elastomer and increase chain branching. The higher the level of filler at the start or selection of a filler having a certain particle size distribution, the higher the degree of compounding and thus more of the elastomeric chains are broken, causing lower viscosity bases and thus softer final gum base and gum made from such a base. The longer the time of compounding, the use of  
20 lower molecular weight or softening point gum base ingredients, the lower the viscosity and firmness of the final gum base.

          Compounding typically begins to be effective once the ingredients have massed together. Anywhere from 15 minutes to 90 minutes may be the length of compounding time.

25           Preferably, the time of compounding is from 20 minutes to about 60 minutes. The amount of added plasticizer depends on the level of elastomer and filler present. If too much elastomer plasticizer is added, the initial mass becomes over plasticized and not homogeneous.

          After the initial ingredients have massed homogeneously and compounded for the  
30 time desired, the balances of the base ingredients are added in a sequential manner until a completely homogeneous molten mass is attained. Typically, any remainder of

elastomer, plasticizer, and filler, are added within 60 minutes after the initial compounding time. The filler and the plasticizer would typically be individually weighed and added in portions during this time. The optional waxes and the oils are typically added after the elastomer and plasticizers and during the next 60 minutes. Then  
5 the mass is allowed to become homogeneous before discharging.

Typical base processing times may vary from about one to about three hours, preferably from about 1 ½ to 2 ½ hours, depending on the formulation. The final mass temperature when discharged may be between 50°C and 130°C and preferably between 70°C and 120°C. The completed molten mass is emptied from the mixing kettle into  
10 coated or lined pans, extruded or cast into any desirable shape and allowed to cool and solidify. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

Examples of the process to make the inventive gum base differ from the typical process and are detailed in the pending Examples below. These are presented to  
15 exemplify embodiments of the present invention and in no way are presented to limit the scope of the present invention.

Gum formulas may comprise from about 10 to about 99 weight percent a gum base made in accordance with the present invention in a gum formula typically known to those in the art.

20 The water-soluble portion of the chewing gum may comprise softeners, sweeteners, flavoring agents and combinations thereof. The sweeteners often fill the role of bulking agents in the gum. The bulking agents generally comprise from approximately 5 percent to about 90 percent, preferably from approximately 20 percent to about 80 percent.

25 Softeners are added to the chewing gum in order to optimize the chewability and mouth feel of the gum. Softeners typically constitute from approximately 0.5 percent to about 25.0 percent by weight of the chewing gum. Softeners contemplated for use in the gum include glycerin, lecithin and combinations thereof. Further, aqueous sweetener solutions such as those containing sorbitol, hydrogenated starch hydrolysates, corn syrup  
30 and combinations thereof may be used as softeners and bulking agents in gum. Sugar-free formulations are also typical.

Sugar sweeteners generally include saccharide-containing components commonly known in the chewing gum art which comprise, but are not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids and the like, alone or in any combination.

5       The sweetener for use in the present invention can also be used in combination with sugarless sweeteners. Generally, sugarless sweeteners include components with sweetening characteristics but which are devoid of the commonly known sugars and comprise, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolyzates, maltitol and the like, alone or in any combination.

10       Depending on the particular sweetness release profile and shelf-life stability needed, bulk sweeteners of the present invention can also be used in combination with coated or uncoated high-intensity sweeteners or with high-intensity sweeteners coated with other materials and by other techniques.

High-intensity sweeteners, or artificial sweeteners and peptide sweeteners as they  
15 may be referred to, typically may include, but are not limited to, alitame, thaumatin, aspartame, sucralose, acesulfame, saccharin and dihydrochalcones. The range of these sweetener types in gum typically may range from approximately 0.02 to about 0.10 weight percent for sweeteners such as alitame, thaumatin and dihydrochalcones, and from approximately 0.1 to about 0.3 weight percent for sweeteners like aspartame, sucralose,  
20 acesulfame and saccharin.

A flavoring agent may be present in the chewing gum in an amount within the range of from approximately 0.1 to about 10.0 weight percent and preferably from approximately 0.5 to about 3.0 weight percent of the gum. The flavoring agents may comprise essential oils, synthetic flavors, or mixtures thereof including, but not limited  
25 to, oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, clove oil, oil of wintergreen, anise and the like. Artificial flavoring components are also contemplated for use in gums of the present invention. Those skilled in the art will recognize that natural and artificial flavoring agents may be combined in any sensory acceptable blend. All such flavors and flavor blends are contemplated for  
30 use in gums of the present invention.

Optional ingredients such as colors, emulsifiers and pharmaceutical agents may

be added to the chewing gum.

In general, chewing gum is manufactured by sequentially adding the various chewing gum ingredients to a commercially available mixer known in the art. After the initial ingredients have been thoroughly mixed, the gum mass is discharged from the mixer and shaped into the desired form such as by rolling into sheets and cutting into sticks, extruded into chunks or casting into pellets.

Generally, the ingredients are mixed by first melting the gum base and adding it to the running mixer. The base may also be melted in the mixer itself. Color or emulsifiers may also be added at this time. A softener such as glycerin may also be added at this time, along with syrup and a portion of the bulking agent/sweetener. Further portions of the bulking agent/sweetener may then be added to the mixer. A flavoring agent is typically added with the final portion of the bulking agent/sweetener. A high-intensity sweetener is preferably added after the final portion of bulking agent and flavor have been added.

The entire mixing procedure typically takes from five to fifteen minutes, but longer mixing times may sometimes be required. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

By way of example, and not limitation, examples of the process to make the inventive gum of the present invention are detailed in the examples below. These are presented to exemplify embodiments of the present invention and in no way are presented to limit the scope of the present invention.

#### EXAMPLES

##### Miscibility of Poly(D,L-lactic acid) and Poly(D,L-lactic acid-co-glycolic acid) with Plasticizers

Selection of the right or miscible plasticizers is an important step to make Poly(D,L-lactic acid) and Poly(D,L-lactic acid-co-glycolic acid) elastic. The inventor screened a number of plasticizers, mostly food-grade ones.

##### **Example 1.**

Poly(D,L-lactic acid) (*courtesy of PURAC Biochem bv, The Netherlands. Its viscosity molecular weight is 42,200 g/mol*) was dissolved in toluene to make a 5 wt% solution. After dissolving, the solution was blended with triacetin at a ratio of 100:1. A

film was cast from the solution blend. After dried at ambient conditions first, then in vacuum, the film was soft, elastic, and transparent. The glass transition temperature (T<sub>g</sub>) of poly(D,L-lactic acid) shifted from 35.8°C (*pure Poly(D,L-lactic acid)*) to 12.8°C as measured on DSC. Therefore, triacetin is a good plasticizer for poly(D,L-lactic acid).

5       **Example 2.**

Same as Example 1 but poly(D,L-lactic acid) solution-to-triacetin ratio was decreased to 100:2. The resulting film was clear and very soft. T<sub>g</sub> determined by DSC was 2.0°C.

Figure 1 is a comparison of DSC curves of Examples 1 and 2 with pure poly(D,L-lactic acid). The measurements were carried out on a Perkin Elmer DSC-7 differential scanning calorimeter (DSC) with a heating rate of 15°C/min.

10       **Examples 3-6.**

Same as example 2 but glycerol, tributyl citrate, acetyl tributyl citrate, and caprylic triglyceride replaced triacetin, respectively. The films were clear and soft for citrates but tough for glycerol and caprylic triglyceride. The clear films indicated that these were good plasticizers.

15       **Examples 7-11.**

Same as Example 2 but different plasticizers were used. It was found that PEG-600 (polyethyleneglycol with molecular weight 600), PPG-4000 (*polypropyleneglycol with molecular weight 4000*), stearic acid, soya oil, and sunflower oil all produced cloudy or oily films which indicated poor compatibility.

20       **Example 12.**

Poly(D,L-lactic acid-co-glycolic acid) copolymer (*containing 50/50 molar ratio of D,L-lactide and glycolide, also courtesy of PURAC Biochem bv, The Netherlands.*) was dissolved in methylene chloride to make a 5 wt% solution. The solution was then blended with triacetin at a ratio of 100:2. A film was cast from the solution blend. After dried at ambient conditions first, then in vacuum, the film was soft, elastic, and transparent.

25       **Examples 13-14.**

Same as Example 12 but PEG-600 and tributyl citrate were used as the plasticizers. The resulting films were soft and clear (*semiclear in the case of tributyl*



*citrate*) indicating good compatibility.

**Examples 15-20.**

Same as Example 12, but different plasticizers were used. It was found that caprylic triglyceride, soya oil, sunflower oil, stearic acid, glycerol, and acetyl tributyl  
5 citrate were not compatible with poly(D,L-lactic acid-co-glycolide).

Table 1 below summarizes the appearance and compatibility of all the plasticized films.

Table 1. Summarizes Visual Miscibility Results of Polymer Films

	Example	Polymer	Plasticizer	Ratio (w/w)	Film Property	Compatibility
5	Control	PdLLA	None		Clear but tough	
	1	"	Triacetin	5:1	Clear and soft	Yes
	2	"	"	5:2	Clear & very soft	Yes
	3	"	Glycerol	5:2	Clear and soft	Yes
	4	"	Tributyl citrate	5:2	Clear and soft	Yes
	5	"	Acetyl tributyl citrate	5:2	Clear and soft	Yes
	6	"	Caprylic triglyceride	5:2	Clear but tough	Partially
	7	"	PEG-600	5:2	Cloudy & tough	No
	8	"	PPG-4000	5:2	Cloudy	No
	9	"	Stearic acid	5:2	Cloudy	No
	10	"	Soya oil	5:2	Oily	No
10	11	"	Sunflower oil	5:2	Oily	No
	Control	PLGA	None		Clear but tough	
	12	"	Triacetin	5:2	Clear and soft	Yes
	13	"	PEG-600	5:2	Clear and soft	Yes
	14	"	Tributyl citrate	5:2	Soft & semiclear	Partially
	15	"	Caprylic triglyceride	5:2	Cloudy	No
	16	"	Stearic acid	5:2	Cloudy	No
	17	"	Glycerol	5:2	Cloudy & oily	No
	18	"	Acetyl tributyl citrate	5:2	Cloudy & tough	No
	19	"	Soya oil	5:2	Oily	No
	20	"	Sunflower oil	5:2	Oily	No

25

### Preparation of Chewing Gum Bases and Gums

#### **Example 21.**

To a laboratory gum base mixer (*Plastograph from Brabender Corp., Rochelle Park, N.J.*) set at 75°C, 35.7 grams of poly(D,L-lactic acid), 14.3 gram triacetin, and  
5 15.0 grams of talc (*mean particle=4.5-5.0 micron*) were added and mixed for 10 minutes, then 10.0 grams of talc and 10.0 grams of tall oil glycerol ester were slowly added while the mixer compounded the polymer. After mixing for 10 more minutes, 7 grams of paraffin wax (*MP=135 F*) and 8 grams of glycerol monostearate were added. The gum base was discharged in 30 minutes (*total*).

10 Figure 2 is a comparison of the rheological properties of this poly(D,L-lactic acid) base and a conventional, PVAc and butyl rubber base. As we can see, both E' and tan $\delta$  are fairly close in the entire temperature range.

#### **Example 22.**

To a laboratory gum mixer set at 55°C was added 22 grams of gum base Example  
15 21 and 35 grams of 6x sugar. After being mixed for 5 minutes, 20 grams of corn syrup and 20 grams of 6x sugar were added. Mix for 5 minutes. Finally, 0.5 grams of lecithin, 0.4 grams of malic acid, 1.5 grams of glycerol (96%), and 0.6 grams of strawberry flavor (Wrigley) were added. Additional 5 min mixing was continued before discharging. The gum had chewing texture like a conventional poly(vinyl acetate) based chewing gum.

20 It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

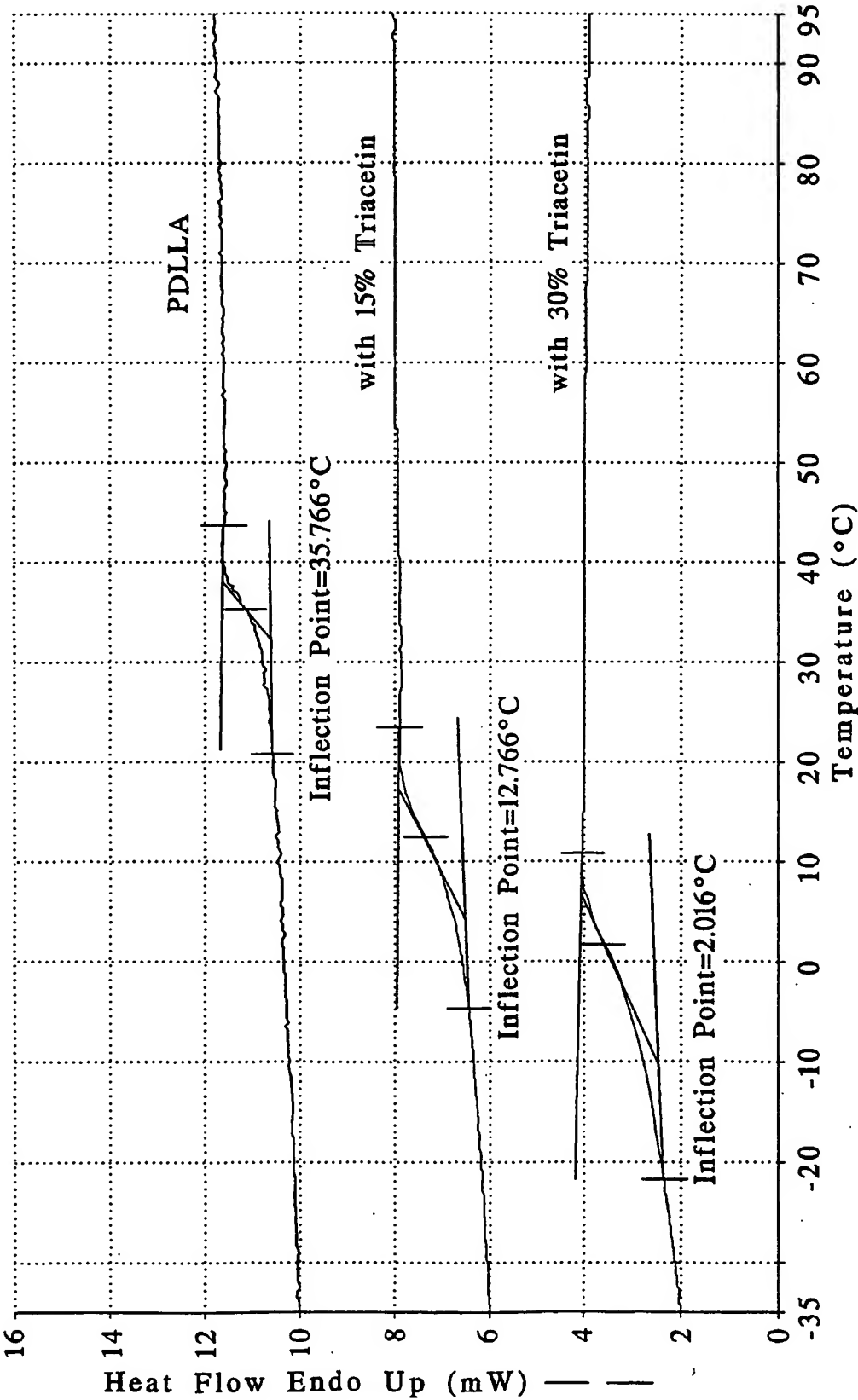
25

CLAIM:

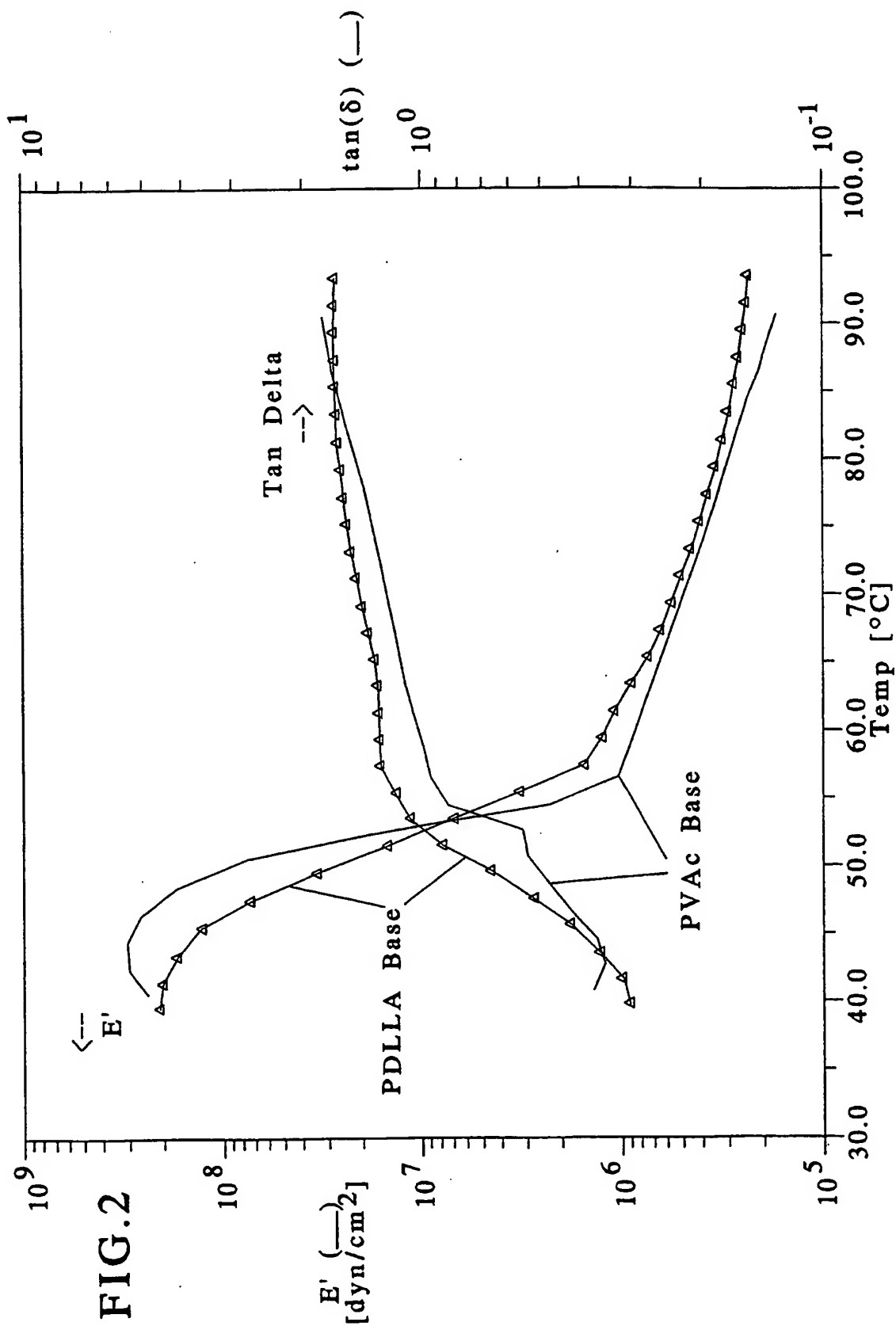
1. A chewing gum comprising:  
plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid).
2. The chewing gum of Claim 1 wherein the plasticized poly(D,L-lactic acid)  
5 and poly(D,L-lactic acid-co-glycolic acid) have a crystallinity of less than about 18%.
3. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid) has a  
crystallinity of less than about 10%.
4. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid) contains  
at least 5 mole percent of at least one component chosen from the group consisting of D-  
10 lactic acid and D-lactide segments.
5. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid) has a  
molecular weight of from 2000 to 2,000,000 g/mol.
6. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid) has a  
molecular weight from 10,000 to 500,000 g/mol.
- 15 7. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid-co-glycolic  
acid) has a crystallinity of less than about 10%.
8. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid-co-glycolic  
acid) includes approximately 20 to about 70 mole percent of at least one component  
chosen from the group consisting of glycolic acid and glycolide.
- 20 9. The chewing gum of Claim 1 wherein the poly(D,L-lactic acid-co-glycolic  
acid) has a molecular weight of approximately 10,000 to 500,000 g/mol.
10. The chewing gum of Claim 1 including at least one plasticizer chosen  
from the group consisting of glycerides (mono-, di-, and tri-), adipates, citrates,  
poly(ethylene glycol), poly(propylene glycol), and phthalates.
- 25 11. A gum base comprising:  
plasticized poly(D,L-lactic acids) and poly(D,L-lactic acid-co-glycolic acid).
12. The gum base of Claim 11 wherein the poly(D,L-lactic acid) has a  
crystallinity of less than about 18%.
13. The gum base of Claim 11 wherein the poly(D,L-lactic acid) contains at  
30 least 5 mole percent of at least one component chosen from the group consisting of D-  
lactic acid and D-lactide segments.

14. The gum base of Claim 11 wherein the poly(D,L-lactic acid) has a molecular weight from 2000 to 2,000,000 g/mol.
15. The gum base of Claim 11 wherein the poly(D,L-lactic acid) has a molecular weight from 10,000 to 500,000 g/mol.
- 5 16. The gum base of Claim 11 wherein the poly(D,L-lactic acid-co-glycolic acid) has a crystallinity of less than about 18%.
17. The gum base of Claim 11 wherein the poly(D,L-lactic acid-co-glycolic acid) includes approximately 20 to about 70 mole percent of at least one component chosen from the group consisting of glycolic acid and glycolide.
- 10 18. The gum base of Claim 11 wherein the plasticized poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) comprises approximately 10 to about 70% by weight of the gum base.
19. A method of manufacturing gum base comprising the step of:  
plasticizing poly(D,L-lactic acid) and poly(D,L-lactic acid-co-glycolic acid) and  
15 adding a resultant product to other gum base components.
20. The method of Claim 19 wherein the resultant product comprises approximately 20 to about 70 weight percent of the gum base.
21. A method of manufacturing chewing gum comprising the step of:  
adding a gum base including plasticized poly(D,L-lactic acid) and poly(D,L-lactic  
20 acid-co-glycolic acid) to a water soluble portion.

FIG.1



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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/20656

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A23G 3/30

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 426/3, 4, 5, 6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
none

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,366,740 A (SHAW ET AL) 22 November 1994 (22-11-94)	
A	US 5,482,722 A (COOK) 09 January 1996 (09.01.96).	
A	US 5,580,590 A (HARTMAN) 03 December 1996 (03.12.96).	
A	US 5,672,367 A (GRUPMA ET AL) 30 September 1997 (30.09.97)	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*B* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 NOVEMBER 1998

Date of mailing of the international search report

15 JAN 1999

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**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US98/20656

**A. CLASSIFICATION OF SUBJECT MATTER:**

US CL :

426/3, 4, 5, 6